

REMARKS

Reconsideration of the application in view of the following remarks is respectfully requested.

Claims 3, 4, and 11-15 are pending and under consideration in the subject application. Of these, there is a single independent claim 3. Claims 4 and 11-15 depend directly or indirectly from claim 3, thus including all the elements of claim 3. No amendments are introduced with this response.

Rejection Under 35 U.S.C. § 102

In the Office Action dated January 25, 2007, claims 3 and 12-15 were rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Wang (U.S. Patent No. 6,379,379). More specifically, at page 2 of the Office Action, Wang was asserted to “disclose a stent graft comprising a stent (44) with grafts (46), wherein the grafts include a vessel wall irritant...” Wang was further asserted to disclose a stent graft that is a self-expandable or balloon-expandable tubular member. Applicants respectfully traverse this ground of rejection and submit that Wang fails to disclose or teach every element of the instant claims.

Claims 3 and 12-15 were asserted to be anticipated by Wang under Section 102(e). As set forth in the Manual of Patent Examining Procedure (M.P.E.P.), for a reference to anticipate a claim under Section 102(a), (b), and (e), the reference must teach every element of the claim (M.P.E.P § 2131).

Claim 3 (and thus claims 4 and 11-15) is directed to a “stent graft, comprising an endoluminal stent and a graft...” Therefore, at a minimum, a “stent graft” requires at least two elements: a stent and a graft. Applicants respectfully submit that, contrary to the assertion in the Office Action, as quoted above, Wang fails to disclose or teach, or even suggest, a stent graft.

Wang fails to disclose or teach a graft, which is a required element of Applicants’ claimed stent graft, and therefore Wang cannot represent an anticipatory reference within the meaning of Section 102(e). Wang discloses merely a stent having at least one smooth end (*e.g.*, Abstract). In the Office Action, it is asserted that the structure associated with reference numeral

“(46)” is a graft. Applicants respectfully point out that this is not correct. In a particular embodiment, Wang discloses a stent (44) wherein the smooth end comprises a “sleeve (46)” that “overlays the end portion(s) of the stent” (*e.g.*, Figure 11; column 8, lines 20-26). A sleeve is not a graft and does not convert a stent into a stent graft. There is a difference between a stent and a stent graft. Stents are small devices that can be inserted into a body passageway (*e.g.*, a coronary artery) to expand, hold open, and/or prevent obstruction of the body passageway. Typically, a stent has metal tines that form a tubular web or open weave (*e.g.*, Figures 1, 4, 5, 11, and 12, and the corresponding description of these embodiments of the stent in the specification of Wang). Therefore, stents act as support structures and need not be fluid-tight. Generally, stents are coated with drugs to prevent the growth of material through the stent tines, thereby preventing stenosis or restenosis (*i.e.*, build-up that can lead to narrowing or re-narrowing of the lumen of a body passageway). Further, as in Figure 11 of Wang, in particular, a smooth end may be provided to reduce irritation or limit damage when deployed into body passageways. This smooth end may be provided as a sleeve, as noted above. A stent graft, in contrast, comprises a graft (*e.g.*, a tube that can function as an alternate body passageway) that has a stent to hold the graft open and to permit attachment of the graft to a body passageway. Hence, the graft material of a stent graft is selected to prevent the flow of fluids from the inside to the outside of the graft. For example, as described in the instant specification, a stent graft can be used to effectively bypass a damaged body passageway (*e.g.*, an aneurysm), while still allowing fluids to flow through the lumen of the graft, but not through the graft walls (*see* page 19, line 10, through page 21, line 18, of the instant specification). Thus, the stent disclosed by Wang could not be used to bypass a damaged body passageway because body fluids would not be rerouted through an alternative body passageway and could flow freely through the open structure of the stent. Thus Wang fails to disclose or teach, or even suggest, a stent graft according to the instant claimed invention.

Accordingly, it is believed that the rejection of claims 3 and 12-15 under 35 U.S.C. § 102(e) has been overcome. Reconsideration and withdrawal of this rejection are respectfully requested.

Rejection Under 35 U.S.C. § 103

In the Office Action, claims 4 and 11 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Wang (U.S. Patent Application No. 6,379,379). More specifically, it is asserted at page 3 of the Office Action that Wang “discloses all the limitations of the claims except fails to disclose a stent-graft being a bifurcated stent-graft and the wall irritant being selected from the groups as listed in claim 4.” This ground of rejection is respectfully traversed.

Claims 4 and 11 depend from independent claim 3, and thus possess all the elements of claim 3. Contrary to the assertion in the Office Action, Wang in fact fails to disclose all the elements of the instant claims. Wang fails to disclose or teach a graft, which is a required element of Applicants’ claimed stent graft. Wang discloses merely a stent having at least one smooth end (*e.g.*, Abstract). In the Office Action, it is asserted that the structure associated with reference numeral “(46)” is a graft. Applicants respectfully point out that this is not correct. In a particular embodiment, Wang discloses a stent (44) wherein the smooth end comprises a “sleeve (46)” that “overlays the end portion(s) of the stent” (*e.g.*, Figure 11; column 8, lines 20-26). A sleeve is not a graft and does not convert a stent into a stent graft. There is a difference between a stent and a stent graft. Thus Wang fails to disclose or teach, or even suggest, a stent graft according to the instant claimed invention.

Now turning to further aspects of the rejection under 35 U.S.C § 103(a), the Action at page 3 asserts that “it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Wang’s stent [emphasis added] having bifurcated configuration in order to treat a bifurcated area in a vessel system.” Applicants submit that, whether or not introduction of a bifurcated configuration would have been obvious, doing so nevertheless fails to remedy the defect in Wang, namely, the absence in Wang of any disclosure, teaching or suggestion of a stent graft. Applicants also submit that the use of the term “stent” in the Action, as emphasized above, suggests that there is a misunderstanding on the part of the Office of the fundamental difference between a stent and a stent graft. These two devices are not interchangeable.

The Action further asserts, with respect to instant claim 4, that “it would have been an obvious matter of design choice to use the bioadhesive material as claimed for Wang’s

stent graft” and that “the bioadhesive materials as claimed would perform equally well as bioadhesive materials disclosed by Wang.” Applicants submit that, whether or not use of the bioadhesive materials of Wang would have been an obvious design choice, doing so fails to remedy the defect in Wang, namely, the absence in Wang of any disclosure, teaching or suggestion of a stent graft. Applicants further submit that the Action has failed to provide support for the suggestion that vessel wall irritants, in general, and specifically those recited in claim 4 (talcum powder, metallic beryllium, and silica), are bioadhesive materials. Applicants respectfully disagree with this assertion and ask that, if maintained, support be provided for this assertion.

Applicants further submit, more generally, that Wang not only fails to teach or suggest the stent graft to which the instant claims are directed, but it actually teaches away from the claimed invention. Instant claim 3 (and thus claims 4 and 11-15) is directed to a stent graft comprising a vessel wall irritant, which, when implanted into a blood vessel, induces or accelerates an in vivo fibrotic reaction at a tissue in the vicinity of the stent graft. That is, the instant stent graft is designed, by virtue of the presence of the irritant, to induce or accelerate a tissue response (a fibrotic reaction), as claimed. In contrast, the stent (not stent graft) disclosed by Wang is specifically designed to prevent damage to or a response by the tissue. In particular, the stent of Wang is disclosed as having end portion(s) with a smooth finish and, in certain embodiments, may release drugs to inhibit tissue responses (*e.g.*, drugs to specifically inhibit fibrotic reactions, such as those listed at column 6, lines 13-23) or bioadhesives for release to repair tissue damaged upon insertion of the stent (*e.g.*, column 6, line 48, to column 7, line 2).

Applicants respectfully submit that the Patent Office has failed to establish a *prima facie* case for obviousness of claims 4 and 11 under Section 103(a). In fact, Applicants further submit that there would have been no basis for an assertion of obviousness of any of claims 3 and 12-15 either.

Accordingly, it is believed that the rejection of claims 4 and 11 under 35 U.S.C. § 103(a) has been overcome. Reconsideration and withdrawal of this rejection are respectfully requested.

Therefore, in light of the remarks set forth above, Applicants believe that all of the Examiner's objections have been overcome. Reconsideration and allowance of the now pending claims (3, 4, and 11-15) are respectfully requested. If there is any further matter requiring attention prior to allowance of the subject application, the Examiner is respectfully requested to contact the undersigned representative (at 206-622-4900) to resolve the matter.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,
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